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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,143	06/21/2006	Ronald James Jandacek	CHM-016	9438
38155 7590 04/16/2009 HASSE & NESBITT LLC 8837 CHAPEL SQUARE DRIVE SUITE C CINCINNATI, OH 45249				
EXAMINER WALLENHORST, MAUREEN				
ART UNIT		PAPER NUMBER		
1797				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/567,143

Applicant(s)

JANDACEK ET AL.

Examiner

Maureen M. Wallenhorst

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-9 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-9, 11-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

1. In response to Applicants' Request for Reconsideration of the Advisory Action received on March 30, 2009, prosecution in the instant application is re-opened in order to institute the following new grounds of rejection. The amendments to the claims filed on March 9, 2009 have been entered.
2. Claims 3-4, 6 and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite since it is not clear what percentage of the marker is present in the composition in view of the recited percentages of the dietary fat, the protein and the carbohydrate portions of the composition. See this same problem in claim 6 that positively recites the percentages of the protein and carbohydrate in the test meal, but fails to recite the percentages of the dietary fat and the marker in the test meal.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (US 5,085,884).

Young et al teach of a reduced calorie food composition comprising a digestible triglyceride fat or oil and a nondigestible fat component. The nondigestible component comprises nondigestible solid or liquid polyol fatty acid polyesters having ester groups comprising combinations of unsaturated (C12 or higher) and/or short chain (C2-C12) saturated fatty acid radicals and long chain (C20 or higher) saturated fatty acid radicals. The nondigestible fat component is a liquid or solid sugar fatty acid polyester, wherein the sugar can be sucrose. The sugar fatty acid polyester contains at least 4 fatty acid ester groups which are nondigestible and consequently non-absorbable by the human body. The sugar starting material of these polyesters are esterified with fatty acids containing from 2 to 24 carbon atoms, preferably 8 to 22 carbon atoms. Examples of the fatty acids include behenic acid, thus making the non-absorbable compound a sugar (i.e. sucrose) behenate. Young et al teach of the manufacture of sucrose C12-C22 polyesters such as sucrose behenate in the examples. See the abstract, lines 20-50 in column 4, lines 15-59 in column 7, lines 1-11 in column 8 and columns

13-14 in Young et al. The reduced caloric food compositions can also include a carbohydrate portion that acts as a bulking agent or a dietary fiber. See lines 55-68 in column 18 of Young et al. The food compositions can also include other nonfat ingredients such as proteins. See lines 22-30 in column 19 of Young et al.

Therefore, the food compositions taught by Young et al include a nondigestible marker that can consist of a sucrose polyester such as sucrose behenate, dietary fat (i.e. triglyceride fat or oil), carbohydrate and protein. Young et al fail to teach of the same percentage amounts of the nondigestible marker, dietary fat, carbohydrate and protein as recited in the instant claims. However, absent any teaching of criticality by the Applicants concerning the amounts listed in claims 3 and 11, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to recognize that these amounts are result effective variables whose amounts can be experimentally varied in order to optimize the food composition for a particular use or for consumption by a particular individual or animal.

7. Claims 5-9 and 13-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Janghorbani et al (US 6,006,754) in view of either Young et al (US 5,085,884) or Jandacek et al (US 4,005,196). For a teaching of Young et al, see previous paragraphs in this Office action.

Janghorbani et al teach of a method and composition for measuring fat absorption. The method aids in evaluating a person for the presence or absence of maldigestion and malabsorption, assists in monitoring the course of disorders underlying maldigestion or malabsorption, and helps clinicians to optimize therapy for individual patients. The method comprises the steps of feeding a person a test meal composition comprising a labeled dietary fat, a non-absorbable, non-digestible marker and a means for coloring stool, allowing the

composition to travel through the digestive tract of the person, monitoring the stool from the person for the appearance of the coloring means, collecting a stool sample containing the coloring means, and measuring the amount of both the non-absorbable marker and the labeled dietary fat in the colored stool to determine the portion of fat digested and/or absorbed by the person. The dietary fat includes a triglyceride, the non-absorbable marker includes a non-absorbable salt containing an element from the lanthanide group, and the coloring means includes a dye such as carmine red. See lines 1-26 and 53-67 in column 3, lines 1-32 in column 4 and lines 24-27 in column 7 of Janghorbani et al. The test meal composition can be provided in a liquid form. See lines 37-40 in column 4 of Janghorbani et al. Janghorbani et al fail to teach that the non-absorbable marker in the test meal can be a sucrose polyester such as sucrose behenate, and that the test meal comprises protein and carbohydrate components in addition to the dietary fat and the non-absorbable marker.

Jandacek et al teach that liquid polyol polyester compounds of sugars or sugar alcohols are non-absorbable and non-digestible, and are often used as fat substitutes in foods. The liquid polyol polyesters comprise a sugar or sugar alcohol esterified with at least four fatty acid groups. The sugar is preferably sucrose, and the fatty acids contain between 8 and 22 carbon atoms. One example of the fatty acid includes behenic acid. When both sucrose and behenic acid are present in the liquid polyol polyester compound, the compound is sucrose behenate. These compounds are non-absorbable and non-digestible by the digestive tract of an individual. See lines 7-68 in column 8 of Jandacek et al.

Based upon the combination of Janghorbani et al with either Young et al or Jandacek et al, it would have been obvious to one of ordinary skill in the art at the time of the instant

invention to use the polyol polyester compound, sucrose behenate, as the non-absorbable, non-digestable marker in the composition and method taught by Janhorbani et al in place of the lanthanide salt marker since the disclosure of Janghorbani et al only requires the marker compound to be non-absorbable and non-digestable by the digestive tract of an individual so that it is excreted in the feces of the individual, and both Young et al and Jandacek et al teach that polyol polyester sugar compounds such as sucrose behenate are both non-absorbable and non-digestable compounds. The substitution of one known element (i.e. sucrose behenate) for another (i.e. a lanthanide salt) that are both non-absorbable and non-digestable would have yielded predictable results to one of ordinary skill in the art at the time of the invention. It also would have been obvious to one of ordinary skill in the art to include both a carbohydrate and a protein component in the test meal composition taught by Janghorbani et al in order to render the test meal more similar to an actual test meal consumed by individuals that usually includes both a protein and a carbohydrate component. In addition, absent any teaching of criticality by the Applicants concerning the amounts recited in claims 6-7 and 17-18, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to recognize that these amounts are result effective variables whose amounts can be experimentally varied in order to optimize the food composition for a particular use or for consumption by a particular individual or animal.

8. Claims 4 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al (US 5,085,884) in view of Janghorbani et al (US 6,006,754). For a teaching of Young et al and Janghorbani et al, see previous paragraphs in this Office action.

Young et al fail to teach that the reduced calorie composition contains a colorant material therein. However, based upon the combination of Young et al and Janghorbani et al, it would have been obvious to one of ordinary skill in the art to include a colorant material such as a dye in the composition taught by Young et al in order to provide an easy means to identify any portion of the composition in the subject's stool after the test composition has been ingested, in accordance with the teaching of Janghorbani et al.

9. Applicant's arguments with respect to claims 3-9 and 11-20 have been considered but are moot in view of the new ground(s) of rejection.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim, can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1797

mmw

April 13, 2009

/Maureen M. Wallenhorst/

Primary Examiner, Art Unit 1797

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